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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/674,955      | 09/30/2003  | Terence Alan Reid    | 7134.US.O1          | 5288             |

7590 03/27/2007  
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| EXAMINER                     |              |
|------------------------------|--------------|
| NOGUEROLA, ALEXANDER STEPHAN |              |
| ART UNIT                     | PAPER NUMBER |
| 1753                         |              |

| SHORTENED STATUTORY PERIOD OF RESPONSE | MAIL DATE  | DELIVERY MODE |
|--|------------|---------------|
| 3 MONTHS                               | 03/27/2007 | PAPER         |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

## Office Action Summary

Application No.

10/674,955

Applicant(s)

REID ET AL.

Examiner

ALEX NOGUEROLA

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 12 January 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-3,5-10,12-14 and 17-22 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3,5-10,12-14 and 17-21 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_.

## **DETAILED ACTION**

### ***Response to Amendment***

1. Applicant's amendment of January 12, 2007 ("Amendment") does not render the application allowable.

### ***Response to Arguments***

2. Applicant's arguments filed January 12, 2007 have been fully considered but they are not persuasive. With regard to the rejections of claims 1-3, 5-13, and 16-21 are being obvious over Hyland under 35 U.S.C. 103(a), Applicant states, "... Hyland et al. teaches that an enzyme should not be in contact with the working electrode." See page 7 of the Amendment. The Examiner respectfully disagrees. To begin with, Hyland states, "The electro-active substance 8 is typically inserted into a receptacle in such a position that the electro-active substance is not in contact with the working electrode. [emphasis added]" See page 10, lines 25-27 of Hyland. "Typically" is not synonymous with "never." Moreover, as discussed in the previous Office action (page 12), the designation "working" electrode in working electrode has no structural or compositional significance, especially since Hyland discloses that the list of possible materials from

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which the working electrode may be made is included in the list of possible materials from which the counter electrode may be made and that the reagent may be deposited on the counter electrode (page 11, lines 7-9). Indeed, the working electrode may be made of Ag/AgCl, which is typically used to make a reference electrode. So in Hyland whether an electrode is actually a working electrode or a counter electrode depends on *how it is used*. In what way is Applicant's working electrode different from Hyland's counter electrode, other than in the labels?

Thus the rejections against claims 1-3, 5-10, 12, 13, and 16-21 are maintained.

***Status of the Rejections pending since the Office action of January 12, 2007***

3. The rejections of claims 1-3, 5-9, 11, 13, 14, 16, 17, 20, and 21 under 35 U.S.C. 103(a) as being obvious over Urban are withdrawn.
4. The rejections of claims 1-3, 5-10, 12-13, and 17-21 under 35 U.S.C. 103(a) as being obvious over Hyland are maintained and have been restated below for Applicant's convenience.
5. The rejections of claims 12, 18, and 19 under 35 U.S.C. 103(a) as being obvious over Urban in view of Fritsch are withdrawn.

***Claim Rejections - 35 USC § 103***

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1-3, 5-10, 12-14, and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hyland (WO 03/056319 A2) ("Hyland").

Addressing claim 1, Hyland discloses an electrochemical cell comprising an insulating substrate (bottom layer 7 in Figures 2 and 3 and bottom layer in Figure 7) and a plurality of layers (Figures 2, 3, 7), the layers comprising at least two conducting layers ((5,6,9,10,10') Also see page 12:30 – page13:2, which discloses up to ten electrodes), and wherein one of the conducting layers is a first electrode (6), the first electrode in contact with at least one reagent ((8) Figures 2, 3, and 7), wherein the at least one reagent comprises an enzyme (page 10, lines 12-23) and at least two insulating layers (Figures 2, 3, and 7), wherein at least one of the at least two insulating layers is interposed between the at least two conducting layers (Figures 2, 3, and 7), wherein each major surface of each conducting layer is in contact with a major surface of the insulating substrate or a major surface of at least one of the at least two insulating layers (Figures 2, 3, and 7), a passage being formed through the at least two conducting layers and the at least two insulating layers to expose edges of the at least two conducting layers and the at least two insulating layers, the edges collectively

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forming a wall or walls of the passage, the exposed edges of the at least two conducting layers forming the working electrode and a second electrode of the electrochemical cell (implied by page 8, lines 10-12; page 4, lines 9-11; and page 12, lines 22-25 of Hyland, which discloses band or ring electrodes or a hole through an electrode).

In Hyland the working electrode is not typically in contact with reagent so the "first electrode" of the previous paragraph would not typically be a working electrode. See bottom paragraph of page 10. However, barring a contrary showing, such as structural or compositional distinctions, the designation of an electrode as a "working" electrode (or counter electrode or reference electrode) is an arbitrary designation only signifying intended use. Hyland discloses that the working electrode and the counter electrode may be made from a variety of materials. The list of materials from which the working electrode may be made is actually included in the list of materials from which the counter electrode may be made. See page 8, second full paragraph and last paragraph, bridging to page 9. Indeed, the working electrode may have an Ag/AgCl layer, which is commonly and traditionally only used for reference electrodes. See page 8, lines 20-23.

Addressing claim 2, for the additional limitations of this claim see Figures 2, 3, and 7 and again note page 12:30 – page 13:2, which discloses up to ten electrodes.

Addressing claim 3, for the additional limitations of this claim see Figures 2 and 3 and again note page 12:30 – page 13:2, which discloses up to ten electrodes.

Addressing claim 5, for the additional limitation of this claim see page 6:1-3 and page 12:20-25.

Addressing claims 6 and 7, for the additional limitations of these claims see page 13, first full paragraph.

Addressing claims 8 and 9, for the additional limitations of these claims see page 12:1-28.

Addressing claim 10, for the additional limitation of this claim see page 12:6-8.

Addressing claim 12, for the additional limitation of this claim see page 7, first full paragraph. Let, for example, the passageway have a depth of 50  $\mu\text{m}$ , a length of 0.1 mm, and a width of 0.1 mm (square cross-section from top view). Then the volume will be 500,000  $\mu\text{m}^3$ , which equals 0.0005 micro liter.

Addressing claim 13, for the additional limitation of this claim see Figures 2, 3, and 7 and page 7, first full paragraph, which implicitly discloses a circular, or square, or rectangular cross-section from a top view.

Addressing claim 14, Hyland only discloses regular shapes for the passage; however, barring a showing of some criticality whether the passage has a regular shape or an irregular shape is just a design choice. MPEP 2144.04 .IV. B.

Addressing claim 17, for the additional limitations of these claims see page 24:1-11 and

Addressing claim 18, for the additional limitation of this claim see page 22:20-24 – page 23:5.

Addressing claim 19, for the additional limitation of this claim see page 23:10-14.

Addressing claim 20, for the additional limitation of this claim see Figure 2. Let the insulating substrate instead be the insulating layer between electrodes 6 and 9, let the insulating layer between electrodes 5 and 9 be the insulating layer of claim 1 that separates at least two conducting layers, and let the insulating layer directly above electrode 7 be the second of the at least two insulating layers of claim 1.

Addressing claim 21, for the additional limitation of this claim see Figures 2 and 3.

Addressing claim 22, for the additional limitation of this claim see page 14, lines 5-10, which discloses providing one or more air holes "... at the point where the base meets the wall of the receptacle, as indicated by the label 12a in Figure 4." These air holes allow air to escape from the receptacle so that the sample liquid can enter.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ALEX NOGUEROLA whose telephone number is (571) 272-1343. The examiner can normally be reached on M-F 8:30 - 5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, NAM NGUYEN can be reached on (571) 272-1342. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Alex Noguerola  
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AU 1753  
March 26, 2007